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OPINION PAPER

Looking beyond effectiveness: Integration of social science research within international infectious disease research in primary care

"Be a good craftsman. Let every man be his own methodologist; let theory and method again become part of the practice of a craft." C. Wright Mills

Sibyl Anthierens

Department of Family Medicine and Population Health, UAntwerpen, Wilrijk, Belgium

KEY MESSAGES

- Incorporating social science research into trial designs with adequate resources and expertise benefits primary care.
- The extent of social science integration in trials affects how findings are contextualised and offers insights into future adoption of effective interventions.
- Interventions should meaningfully resonate with healthcare professionals and patients to effectively drive changes in primary care.

ABSTRACT

Background: As researchers in primary care, we want to drive change in practice and conduct research that sparks meaningful transformation. These changes can only happen if our research work resonates in a meaningful way with the people who they are designed for, i.e. the healthcare professionals and the patients.

Viewpoint: This viewpoint stems from first-hand insights gained as a social scientist engaged in trials and primary care research amidst epidemics and pandemics. Some examples stemming from the EU Funded GRACE INTRO, RECOVER and Prudence trial illustrate these experiences.

I outline how primary care can effectively address the pressing challenges it encounters, whether as researchers, members of the public, or healthcare professionals, and how to integrate successfully social sciences within clinical primary care research.

Conclusion: As interdisciplinary researchers, social scientists and medical researchers can work together under certain conditions, i.e. equal status, adequate resources, and seamless integration within trial structures.

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Introduction

When making value-based healthcare decisions, it is important to shift the focus towards demonstrating value, aligning with the growing importance of healthcare professionals' and patients' experiences. Patient insights, alongside those of healthcare providers and policymakers, can be pivotal in translating trial results into practice and policy. However, human behaviour is messy and difficult to measure. Social science research, then, may enhance and strengthen trials in manifold ways. By integrating social science methodologies alongside traditional clinical trial frameworks, we can uncover the underlying mechanisms driving behaviour and adoption rates. Crucially, social science research – notably qualitative process evaluations – can support the implementation of complex interventions by exposing the contexts and the social and behavioural processes that may derail or amplify their success [1,2]. Moreover, integration of social science methodologies not only enriches trial outcomes but also

CONTACT Sibyl Anthierens Sibyl.anthierens@uantwerpen.be Department of Family Medicine and Population Health, UAntwerpen, Doornstraat 331, 2610 Wilrijk, Belgium.

facilitates the seamless integration of interventions into diverse healthcare settings.

I advocate for social scientists to be granted the recognition and integration they rightfully deserve within the field of infectious diseases within primary care research to enhance the field for all. In primary care, we urgently need to identify more effective ways of diagnosing and treating patients with serious or minor respiratory tract infections. Improving the fit between trials and real world practice is an urgent matter, as we must revolutionise how we diagnose and treat infections in primary care, from the common cold to COVID-19 like infections. Antimicrobial resistance and pandemics are paramount global health crises, reshaping our healthcare landscape.

Clinical research is a crucial element in addressing these problems. Randomised Controlled Trials (RCTs) can play an important role in building scientific knowledge and useful predictions. There is a surge in these clinical trials, evaluating the efficacy of antimicrobial resistance stewardship interventions - such as rapid diagnostic testing or patient leaflets to support a non-antibiotic prescribing decision. While proving safety and efficacy is crucial in trials, Chris Butler has clearly illustrated that we need to move clinical research in primary care further to make it relevant for all and strengthen our evidence [3]. Moreover, translating these findings into widespread clinical practice and policy remains significantly challenging. Many interventions to support better prescribing have been shown to be effective in a trials context, but are not used in routine care [4]. Insight in the various reasons behind this gap, exploring why things work or do not work is crucial. Furthermore, it is important to explore effective implementation strategies for interventions in daily practice, particularly when these interventions are perceived beneficial by clinicians and patients and align with their contextual preferences.

This personal viewpoint is based on a plenary talk delivered at the World Organisation of Family Doctors (WONCA) Europe conference in Brussels in June 2023. I will describe how to successfully integrate social sciences within clinical primary care research, and discuss some of the myths that may hamper this incorporation. I will illustrate this with some examples stemming from the EU Funded GRACE INTRO [5–9], RECOVER [10–12] and Value-DX [13, 14]. This viewpoint stems from first-hand insights gained as a social scientist engaged in trials and primary care research amidst epidemics and pandemics. It outlines how primary care can effectively address the pressing challenges we encounter, whether as researchers, members of the public, or healthcare professionals.

As interdisciplinary researchers, we can work together under certain conditions, which I will describe more in detail.

Different paradigms

Although the academic medical community saw the value of social science before the pandemic and we have seen some success stories – for example, the introduction of process evaluations of trials introduced by the Medical Research Council framework [11], this value not always has been acknowledged. In addition, often social science expertise was not integrated properly. Few trials incorporate a skilled diverse social science team, and those that do may not realise their full potential. While the reasons for this are complex and multifactorial, at the basis lies the difference in research paradigms.

Clinical trials are based within a positivist paradigm that assumes the existence of a single, fixed reality and the possibility of neutral, objective and value-free knowledge of that reality. It is these measurement ideals, embodied in RCT methodology, that assure the RCT evidence is at the heart of evidence-based medicine (EBM) [13]. However, it is these very same ideals and methodological assumptions that lead some social scientists criticise the RCT (and EBM more broadly). Social science research within trials is grounded in the understanding that there is no fixed controlled reality; rather, individuals and groups through their interactions and interpretations within specific contexts construct social realities. Social science research acknowledges the subjectivity of human experience and the importance of interpretation in understanding social phenomena. It adopts interpretive approaches that emphasise the meanings individuals attach to their actions and experiences, and how these meanings shape social interactions and structures. By delving into these social realities, researchers can attain a deeper and more nuanced comprehension of the phenomena under study [1, 2, 15].

Social science research - with its acknowledgment of the subjectivity of human experience and emphasis on interpretive approaches - provides a lens through which researchers can delve into the social realities shaping medical interventions. The resulting deeper understanding enables researchers to appreciate the complexity of individual human behaviour (primary care professionals and patients) and societal dynamics. This understanding is crucial for enhancing the quality of medical interventions. Every intervention, whether a drug, a test, or a strategy to promote practice change, is inherently complex. Even seemingly straightforward

actions like taking medication or using a diagnostic test entail complex behavioural challenges. For instance, phase-3 drug trials in primary care assess effectiveness in real-world settings where habits, social norms, and contextual factors all play pivotal roles. Incorporating social science paradigms into trials facilitates a holistic understanding of these interventions, recognising that their success hinges not only on clinical efficacy but also on their compatibility with societal realities. This nuanced perspective is essential for designing interventions that are not only effective in controlled settings but also adaptable and sustainable within the dynamic landscapes of primary care.

Expanding the role of social science research

The momentum is building to move forward especially with the silent global pandemic of antimicrobial resistance. Of course, there are many challenges to expanding the role of social science research within the clinical trial context. Nevertheless, there are highly warranted grounds for doing so as exploring human behaviour of primary health care professionals and patients within a specific setting is crucial for intervention uptake. As the size and the pace of the epidemics increase, just as antimicrobial resistance, the character and the context continue to change. The success of antimicrobial stewardship interventions - i.e. strategies and programs designed to promote the appropriate and responsible use of antimicrobial agents, such as antibiotics, antivirals, and antifungals - or their implementation strategies, will depend in part on our ability to incorporate them into our guidelines and into daily practice. In addition, it is important to explore how effective we are in reaching the groups that might benefit the most from our interventions, whether it is the healthcare practitioner, the patient or the policy makers. We need to find ways to empower patients and healthcare practitioners to use the tools effectively within their specific context.

Also within trials as social scientists, we need to seek to explain why people act in the way they do, taking account of wider influences such as cultural norms or economic constraints. If we just think back about the recent 'intervention' of social distancing or other prevention measures to prevent spreading of infectious diseases, it sounds a simple intervention but it has proven that it is not that easy to implement. While information provided by public health authorities on infection control is important for transmission prevention, information alone is generally insufficient for people to adhere to recommendations, but require a substantial change in behaviour away from normal routines. Recommendations require people to adopt new behaviours or adjust everyday habits and routines. The extent to which people comply with necessary adaptations is influenced by many factors, including their perception of infection risk, their beliefs about the effectiveness of advice provided, their access to necessary materials and social norms. Therefore, as scientists we cannot wait any longer to use complementary insights achieved through diverse methods and diverse disciplines, sacrificing the aim for a black and white picture of a problem for a more robust understanding of it in order for interventions to be usable in daily practice.

Social science research enriches clinical trials

There is no doubt that clinical trial research places tremendous demands on all who are involved, including participants and staff. Consequently, integrating social science components requires careful consideration; the team should add value and not burden the trial. The clinical trial team, in collaboration with social scientists, should assess their confidence in identifying and recruiting appropriate participants, anticipate any concerns participants may have, determine the necessary data requirements, and consider how contextual factors may impact intervention usage [13].

While international RCTs are crucial, it is also important to acknowledge that the healthcare context may differ between sites and that this might lead to different results. A tangible example: during an international RCT investigating the efficacy of diagnostic tests for judicious antibiotic prescribing in respiratory tract infections, as social scientists we observed that the organisational structure of healthcare varied across trial sites, influencing patients' perceptions of the diagnostic test. In Georgia, through interviews conducted with participants, it emerged that patients seeking care for acute infections in primary care encounter a plethora of available tests, largely owing to the organisational setup of their primary care facilities. Particularly in the capital city, where a significant portion of the population resides, primary care practices resemble mini hospitals, complete with in-house laboratories. Consequently, patients consulting for respiratory tract infections often find themselves undergoing blood tests as a routine procedure. Moreover, during the trial period, patients received additional CRP tests, further adding to the array of diagnostic procedures. However, for patients, discerning the purposes of these tests proved to be a daunting task, as the distinction between them remains unclear [15].

This example underscores the importance of considering the implications of the trial findings, particularly

concerning the potential rollout of these diagnostic tests. It prompts us to reflect on whether there is added value in implementing these tests and, if so, how this value manifests if trial results are effective. Therefore, it is important that when conducting trials we incorporate contextual research findings into our explanations of trial results in order to ensure accurate and meaningful interpretations. It is essential to recognise that interventions are not static; they can be refined and adapted to suit different contexts and accommodate the lived experiences of participants. By embracing these contextual nuances, we can optimise the effectiveness and relevance of interventions in real-world settings.

Conditions to be an equal research partner

Social scientist often work as an undervalued addition to studies. This undervaluation may well stem from the scheduling constraints imposed within an RCT design or from limited funding allocated to the qualitative research elements. Therefore, it is crucial to properly build the social science research work into the design of the trial from the outset. Proper coordination of clinical trial and social science research efforts from the outset is crucial. This coordinated approach should be carefully planned during the project writing stage, when designing the protocol and allocating the budget. Thorough planning ensures that key questions are not duplicated and that the quantitative and qualitative studies comprehensively assess the intervention's impacts, complementing each other's findings. By integrating these research components from the initial planning phase, the overall project can provide a holistic understanding of the intervention's effects.

It is important to provide sufficient resources and proper social science expertise throughout. To realise the full potential of social science work in trials in primary care, it is essential that as an interdisciplinary team we prioritise how trial funding, structure and day-to-day working arrangements will enable and promote effective collaborative working.

As researchers within primary care research, we need to invest in capacity building for social science expertise. Having some experience in qualitative research enriches your understanding, but being a social scientist entails broader expertise and skills then using standard methods, such as interviews and focus groups, rather than the full range of qualitative approaches [3, 4]. It is a distinct profession that demands comprehensive training and qualifications to effectively contribute and we need to foster collaboration and integration between skilled social scientists and medical professionals within primary care research.

Real integration is not just about the data, it is also about the team culture. It is about creating a team dynamic where every member's expertise is valued and respected. It is about senior investigators championing collaboration and diversity of thinking. It is about ensuring that every piece of the puzzle contributes to a greater whole if we want to tackle complex problems within primary care like the silent pandemic. The level of 'embeddedness' of the social science research within the trial will influence how the trial's social science findings can expand and or uphold its overall contribution. We need to come to the full benefit of the integration of the interdisciplinary data, integration that allows for other benefits to emerge from working together.

The goal of 'mixed-methods' approach

Protocols should explicitly outline the integration of social science research findings with quantitative trial outcomes to achieve the trial's core objectives and facilitate potential implementation post-trial. The true integration of trial results and the results from the social science's data stands as the cornerstone of evidence based practice.

Adopting a true mixed-methods approach that seamlessly combines quantitative and qualitative data collection is crucial for enriching outcomes and ensuring no valuable nuances are overlooked. While many studies of complex interventions utilise both quantitative and qualitative components, the majority report these analyses separately without integrating the findings. Triangulation coding can highlight where different viewpoints converge or diverge [7], but simply being aware of agreements and disagreements between datasets is insufficient. The actual merging of data across disciplines within a trial is often neglected, especially as projects near completion.

This oversight stems from the different studies being treated as a separate work packages rather than integrated parts of a unified mixed-methods design. For pragmatic reasons like differing researcher expertise and perceived time/cost efficiencies, independent teams tend to work in methodological silos on their respective quantitative or qualitative datasets. However, this siloed approach represents a failure to fully capitalise on the core tenet of mixed-methods research - the synthesis of different but complementary data sources into a comprehensive understanding greater than the sum of its parts. Neglecting this critical integration step results in a considerable loss of invaluable insights that the mixed-methods approach is specifically intended to provide.

Ideally, qualitative and quantitative findings from mixed-methods studies would be published together

as an integrated series in one journal, maximising their combined value. However, the quantitative trial results often get published in top medical journals like The Lancet, Nature, or BMJ, while successfully publishing the accompanying social science work within those same trials proves considerably more challenging, resulting in that qualitative component appearing in other, lower-impact journals.

Neglecting to fully triangulate and synthesise the quantitative and qualitative findings risks overlooking crucial evidence that could significantly improve future uptake and implementation. The integrated insights from combining these different but complementary data sources offer a comprehensive understanding not just of the intervention outcomes, but also illuminate the underlying mechanisms and contextual factors influencing those outcomes. Ignoring this vital integration step deprives researchers, practitioners, and policymakers of critical insights into what might catalyse real-world progress, innovation in practice, and the opportunity to develop robust implementation plans grounded in a holistic evidence base.

Illustrative examples

Practical examples from our international research demonstrate how a social science perspective can frame evidence, improving actionable findings that directly impact daily clinical primary care practice or policy implementation.

In various trials across our primary care research network [9, 13, 14], we tested the efficacy of introducing point-of-care diagnostic tests to optimise antibiotic prescribing for acute infections. Integrating such tools into routine practice to promote prudent prescribing is complex, as these are multi component interventions where pinpointing the key drivers of effectiveness is difficult.

We purposefully selected countries across Eastern, Southern, and Western Europe to capture diversity in healthcare systems and contexts where diagnostic testing implementation could be useful. Choosing networks/countries required accounting for future implementability – ensuring engagement of healthcare professionals, patients, and policymakers from the outset.

A crucial consideration was how patients' care-seeking behaviours, consultation expectations, primary care access, provider payment models, and contextual factors like sick note requirements [11, 14] might vary across contexts like the UK, Spain, Poland, and Belgium. Exploring such socio-cultural differences was vital for understanding barriers and facilitators to implementation. Our mixed-methods approach elucidated these nuances underlying the quantitative findings on intervention effectiveness.

The social science components examined aspects like participants' comprehension of test instructions, how instruction delivery and provider access influenced utilisation, and potential unintended consequences. For example, misinterpreting results could increase rather than decrease antibiotic prescribing due to added uncertainty. Alternatively, GPs may use tests as communication tools to justify withholding antibiotics [8], or use them for unintended purposes - risking overprescribing, medicalisation, or patients seeking care just to get tested.

Moving forward

It is important to evaluate the intervention's relevance for patients and GPs, and how policy could streamline implementation via adequate reimbursement models. We need to assess real-world adoption by evaluating achieved benefit levels across groups. If clinicians only accept testing aligning with their clinical judgement, the impact on prescribing behaviours will be limited. Some studies indicate scepticism, with clinicians perceiving little added value over their assessments and preferring to trust their judgement. Logistical barriers like workforce and time constraints are also acknowledged.

There is little value scaling interventions that clinicians will not use as intended or patients will not accept, unless we construct a compelling narrative aligning with stakeholder beliefs [10].

To better integrate evidence into practice from the outset, social sciences can play a crucial role by engaging key stakeholders across levels. If an intervention proves effective under trial conditions, it's essential to understand factors encouraging real-world adoption and how policy can facilitate this process.

Conclusions

If primary care researchers from different disciplines truly collaborate as equal partners, think outside disciplinary silos, and foster an inclusive environment to jointly tackle complex problems, we can solve some of the most pressing issues we face today. The key is synergistically merging methodologies to gain a more comprehensive understanding.

An interdisciplinary approach means a team of skilled social scientists with diverse specialties (e.g. behavioural scientists, sociologists, implementation scientists) working alongside the clinical trial team. No single member fully understands all aspects of the problem, but together they can leverage their complementary expertise.

Primary care researcher's ultimate goal goes beyond publishing in journals; it's about driving meaningful transformation in primary care practice. For our interdisciplinary work to resonate and create impact, it must speak directly to the healthcare professionals and patients it is designed to benefit.

Real-world change can only happen if we deeply understand stakeholder perspectives and contexts through mixed methods research. Then our integrated evidence base can inform implementation strategies that effectively navigate barriers and facilitate adoption of new practices or interventions where it matters most - in routine clinical care (Box 1).

Box 1. How to bring together the best of both worlds – clinical and social science research - to drive primary care research forward.

Social science research enriches clinical trials by offering valuable insights without adding undue burden

- By delving into societal and behavioural dynamics, social science paints a fuller picture of interventions in primary care
- Success of an intervention not only depends on its clinical effectiveness; its match with real-world contexts is as important
- Essential for driving change in primary care practice is that interventions have a meaningful resonance with healthcare professionals and patients
- These insights not only boost uptake but also reduce research waste, ensuring every study yields valuable results

Conditions needed to elevate social science research to its rightful place alongside clinical studies

- Availability of skilled social science expertise
- Proper integration and planning of the social science contributions into the research protocol from the start
- Availability of adequate resources
- Coordination of clinical and social science research
- Collaborative working of all disciplines
- Creation and maintenance of a Team Culture

Unlocking the power of mixed methods

- Integration of qualitative and quantitative perspectives is key
- Therefore, teams should unite to blend their expertise and not work in silos
- The degree of integration of social science input within a trial influences how findings are contextualised; that provides valuable insights into the future uptake of the intervention(s)
- To achieve the trial's core objectives and facilitate potential post-trial implementation, protocols should explicitly outline the integration (triangulation) of qualitative (social science research) findings with quantitative trial outcomes
- Publishing trial results alongside social science data could be a game-changer as this could be a catalyst for wides

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